DEUS TECHNOLOGIES, LLC

RapidScreen RS-2000

Radiological Devices Advisory Panel

March 5, 2001

Clinical Presentation

William Sacks, PhD, MD

RapidScreen

CAD ~ ROIs

PA/AP CXRs

SPNs ~ CA

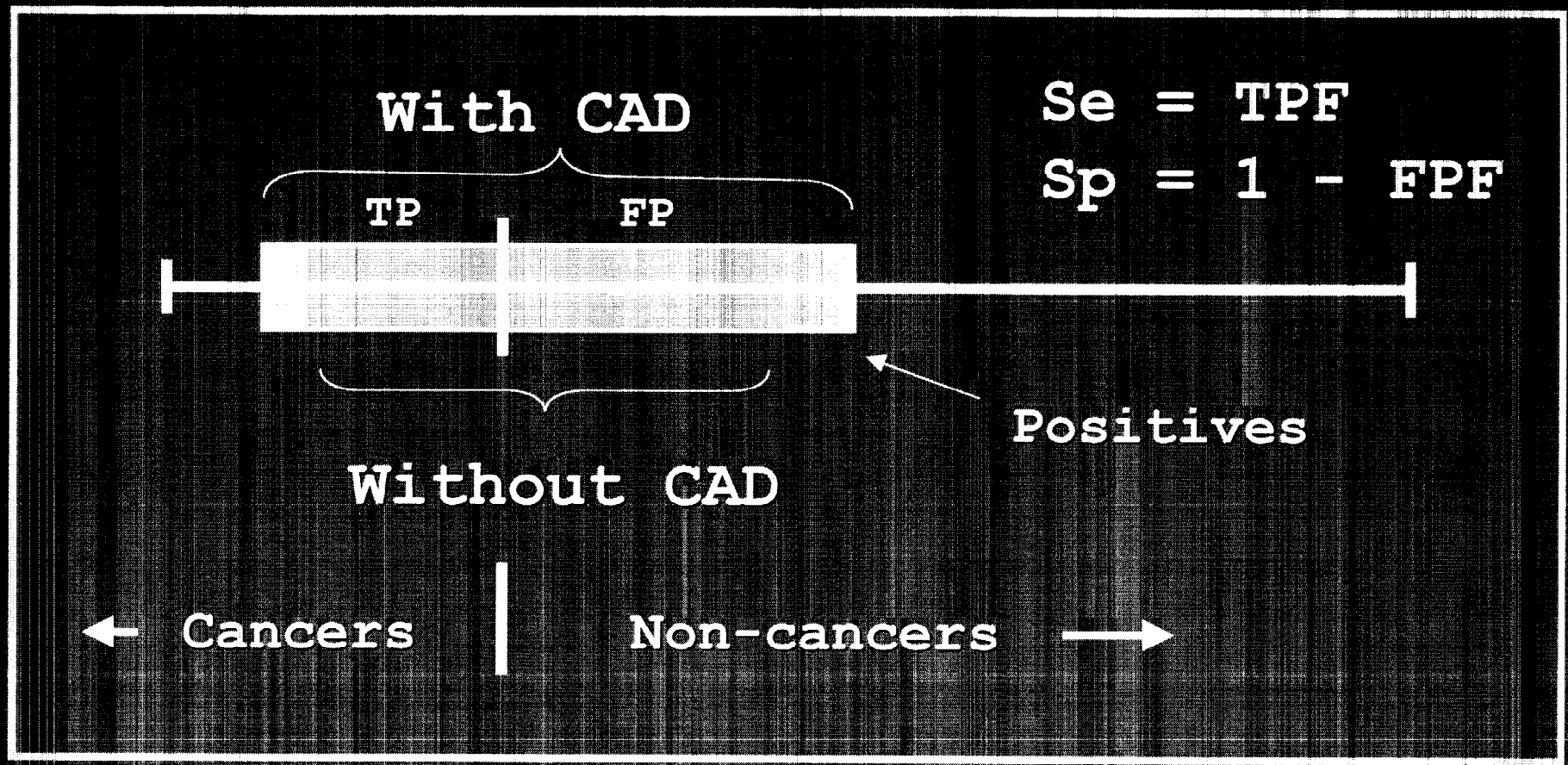
RapidScreen

A Computer Aided Detector (CAD) for identification of regions of interest (ROIs) on frontal views of plain Chest X-Rays (CXRs) to improve detection of Solitary Pulmonary Nodules (SPNs) that could represent lung cancer

Computer Aided Detection (CAD) / Diagnosis (CADx)

CAD	CADx
Detection	Differentiation
↑ Sensitivity	↑ Specificity
↓ FNs (missed cancers)	↓ FPs (work-ups of LTBs)
Scans entire image	Scans portion indicated
Entire population	Only on selected
Errors of detection	Errors of interpretation

↑Sensitivity (↑TPF), but ↓Specificity (↑FPF)



Lung cancer screening has not been recommended, because there has been no effective treatment for cancers once they are visible on CXR. However, treatment has been improving, giving rise to a search for better screening methods.

WHY LUNG CANCERS ARE MISSED ON CXR (false negatives):

Errors of detection → 55%

- Failed to look at → 30%
- Failed to recognize → 25%

Errors of interpretation → 45%

- Kundel HL et al. *Visual scanning, pattern recognition and detection.* Investigative Radiology 1978; 13:175-181.
- Kundel HL. *Predictive value and threshold detectability of lung tumors,* Radiology 1981; 139:25-29.

Non-clinical trial

To assess reproducibility of image digitization and detection of ROIs.

Clinical Trial

To assess changes in radiologists' sensitivity and specificity for detection and discrimination of lung cancers.

Non-clinical trial

3 systems digitized and scanned

60 cancer-containing CXRs

10 times each

(1800 digitization/scans):

Mean device sensitivity 80%

Mean SD of device sensitivity 4.5%

95% CI (71.2%, 88.8%)

Clinical trial

15 radiologists - 240 CXRs:
80 cancers + 160 non-cancers

Good quality 2-view CXRs
25-year-old
lung cancer screening trial by
- Mayo Clinic
- Memorial Sloan-Kettering
- Johns Hopkins University

CANCERS:
Actionable Priors

18/80 cancers were missed by two clinical radiologists.
A Radiologist Expert Panel retrospectively judged them to be actionable.

CANCERS: Currents

62/80 cancers were seen by one or both clinical radiologists. Those missed by one could also be considered Priors - number?

Trial hypotheses

Primary null hypothesis: Device will not improve the sensitivity of the 15 radiologists for detecting lung cancers on all 80 cancer-containing CXRs.

Secondary null hypotheses 1: Same applied to only the 18 Priors.

Secondary null hypotheses 2: Same applied to the 9-14 mm cancers (n=38).

Three readings

1) Independent-without-CAD(IwoC)

(then at least one month later)

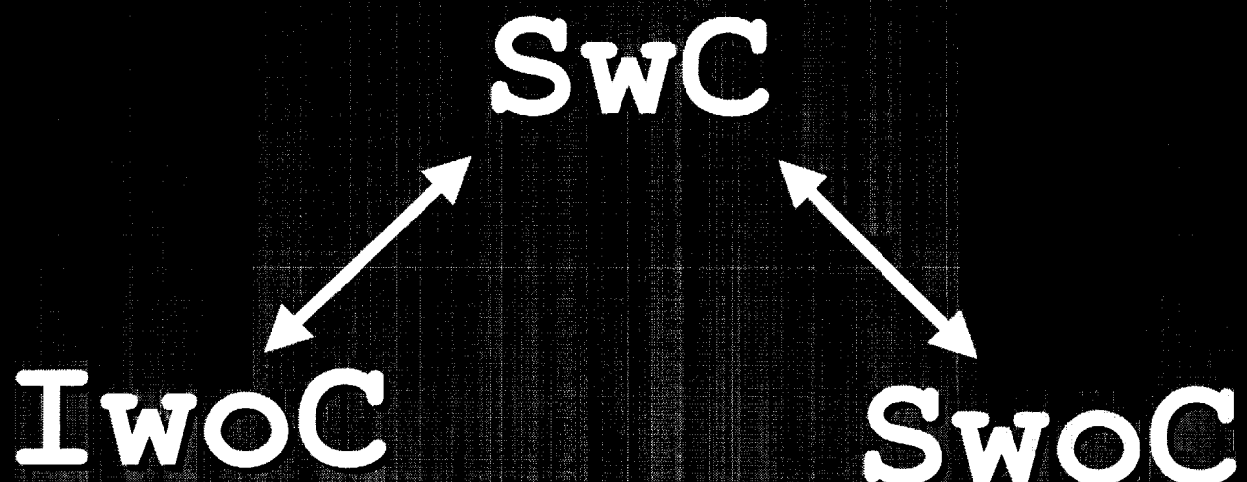
2) Sequential-without-CAD (SwoC)
(immediately following)

3) Sequential-with-CAD (SwC)

Training

Radiologists trained twice: once before IwoC and again before SwoC. Only 8 CXRs used in training sessions.

Comparisons



Readings by radiologists

1) They recorded the probability (0-100%) that each CXR contained a cancer.

2) For each CXR requiring further work-up, they indicated CT or biopsy.

End points

1) The probability ratings were used to construct ROC curves.

2) The sensitivities and specificities at 50% probability were determined.

Clinical Significance

If location of the lesion is ignored, there was a small increase in average reader sensitivity with the CAD, and a small increase in work-ups of benign lesions that preserved PPV. If location of the lesion is taken into account, the gain in sensitivity was smaller and the increase in work-ups larger, with a decrease of PPV.